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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,522	04/16/2004	Geert Plaetinck	D0590.70011US02	2890

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/826,522

Applicant(s)

PLAETINCK ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41, 55 and 57-79 is/are pending in the application.
- 4a) Of the above claim(s) 55, 57-69 and 75-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-41 and 70-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/347,311.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/16/04; 5/22/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application has been transferred to Examiner Quang Nguyen, Ph.D. in GAU 1633.

Applicant's amendment filed on 10/18/06 was entered.

Claims 30-41, 55 and 57-79 are pending in the present application.

Applicant's election without traverse of Group I, drawn to a micro-organism comprising a vector that produces a double stranded RNA molecule, in the reply filed on 10/10/06 is acknowledged.

Accordingly, claims 55, 57-69 and 75-79 were withdrawn from further consideration because they are directed to a non-elected invention.

Claims 30-41 and 70-74 are examined on the merits herein.

Specification

The abstract of the disclosure is objected to because it contains a legal phraseology "said" throughout the abstract, such as said library, said cell, said transcription factor. Correction is required. See MPEP § 608.01(b).

Sequence non-compliance

The disclosure is objected to because the nucleotide sequences in Figure 1 and Figure 2 of the instant specification were not assigned with any SEQ ID Nos in either the Brief Description of the Figures or in the Figures. However, it is noted that a sequence listing containing these nucleotide sequences has been submitted.

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Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-38 and 70-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37, 70 and their dependent claims are vague and indefinite in that the metes and bounds of the term "derived from" are unclear. It is unclear the nature and number of steps required to obtain a "derivative" of the DNA sequence. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the DNA sequence from the source that it is "derived from". It would be remedial to amend the claim language to use the term "obtained from", which implies a more direct method of acquiring the DNA sequence.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30, 32-34, 37-41 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Alderete (US 5,679,551).

Alderete already taught the cloning of a satellite dsRNA s1 or s1' into the pGEM4Z vector containing T7 and SP6 promoters, and the recombinants were transformed into competent *E. Coli* JM109 cells (see at least example 5, particularly col. 18, lines 10-38). Due to the vagueness of the term "derived from", the cDNA sequence encoding the satellite dsRNA s1 or s1' can be considered to be a derivative of a DNA sequence derived from *C. elegans* or from a pest.

The transformed *E. Coli* JM109 cells containing a pGEM4Z vector containing a cDNA sequence encoding the satellite dsRNA s1 or s1' are indistinguishable from a micro-organism as broadly claimed. Additionally, please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*. Whether the rejection is

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based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the **PTO's inability to manufacture products or to obtain and compare prior art products**. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the reference anticipates the instant claims.

Claims 30-41 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Timmons et al. (East Coast Worm Meeting Abstract 180, May 12, 1998; IDS) as evidenced by Timmons et al. (Nature 395:854, 1998; IDS).

Timmons et al. (East Coast Worm Meeting Abstract 180) disclosed that bacteria expressing GFP or unc-22 dsRNA being fed to myo3::GFP worms or *C. elegans*, and a reduction in muscle cell GFP expression was observed in animals fed bacteria expressing dsGFP RNA while animals grown on bacterial expressing unc-22 RNA showed no loss of GFP expression but they exhibited a weak twitching phenotype. The used bacteria expressing GFP or unc-22 dsRNA are *E. Coli* containing a plasmid vector designed for bidirectional transcription by bacteriophage T7 RNA polymerase as evidenced by the teachings of Timmons et al. (Nature 395:854, 1998; IDS) describing the same studies.

Additionally, please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the

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prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the **PTO's inability to manufacture products or to obtain and compare prior art products**. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, the reference anticipates the instant claims.

Claims 30, 32-39 and 70-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559 B1 with an effective filing date of 12/23/1997; IDS).

With respect to the embodiments with an effective filing date of 12/23/1997, Fire et al already disclosed an *ex vivo* or *in vivo* process of introducing an RNA into a living cell to inhibit gene expression of a target gene in that cell, wherein the RNA has a region with double-stranded structure and that the cell can be a plant, an animal, a protozoan, a virus, a bacterium or fungus cell (see at least Summary of the Invention). Fire et al further teaches that RNA may be synthesized either *in vivo* or *in vitro*, and cloned RNA polymerase can be used for transcription *in vivo* or *in vitro* or endogenous RNA polymerase of the cell may mediate transcription *in vivo* (col. 4, lines 62-67; col. 7, lines 42-52; col. 8, lines 13-19). Fire et al further discloses that for transcription from a transgene *in vivo* or an expression construct, a regulatory region may be used to

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transcribe the RNA strand or strands. Fire et al further teaches that the RNA may be synthesized by a cellular RNA polymerase or a bacteriophage RNA polymerase such as T3, T7 and SP6 (col. 8, line 62 continues to line 25 of col. 9). An exemplified dsRNA is unc-22 dsRNA.

The teachings of Fire et al meet every limitation of the instant claims. Therefore, the reference anticipates the instant claims.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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Quang
QUANG NGUYEN, PH.D.
PATENT EXAMINER